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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,181	11/10/2000	Steven D. Jensen	7678.350.2	4245

22913 7590 08/08/2003

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	14

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/710,181	JENSEN ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-15 and 17-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-15 and 17-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25,30-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating sensitivity (gum, tongue, throat), does not reasonably provide enablement for preventing said sensitivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make / use the invention commensurate in scope with these claims. The asserted utility is not believable on its face. It is not known how a method wherein a composition is claimed can be administered to prevent said sensitivity. The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent said sensitivity. The level of ordinary skill in the art is high but only in the art of treating said sensitivity. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicant. In the instant invention the predictability is very low and consequently, the

need for the higher levels of direction and guidance by the applicant. However, the amount of direction and guidance provided by the applicant is limited to treatment. There is no evidence in the specification that established correlation between the experiment and the claimed utility. The quantity of experimentation required to use the method as claimed in the instant invention, based on applicant's disclosure would be undue because, one of ordinary skill in the art would have performed significant amount of experiments.

Election Status

The elected composition / method comprising carbamide peroxide and potassium nitrate dispersed in carboxypolymethylene and glycerine is not allowable. See art rejections and double patenting rejections below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15,17-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 5851512; 12/22/98). Fischer teaches a dental composition comprising 0.1-10% desentizing agent dispersed in a matrix. See abstract, column 3 lines 40-42. The matrix can be a mixture of carboxypolymethylene (0.5-20%) and glycerine (20-85%). See column 3 lines 57-58, column 4 lines 14-24. The desentizing agent is potassium nitrate. See column 4 lines 25-51. Carbamide peroxide is added to the composition. See

column 9 lines 36-47. Fischer teaches that fluorides salts (0-1%)such as stannous fluoride can be added to the composition. See column 9 lines 1-17. Fischer also teaches that stabilizers such as EDTA (0-1%) are added to the composition to act as ion scavengers. See column 9 lines 28-35. Fischer teaches that the composition is applied to teeth for desensitizing and whitening teeth. Fischer teaches the that the composition can be applied to teeth by way of a dental tray. See column 11 line 39 – column 40 lines 49.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-15,17-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Fischer (US 5985249; 11/16/99). Fischer teaches a dental composition comprising a desentizing agent dispersed in a matrix. See abstract. The matrix can be a mixture of carboxypolymethylene and glycerine. See column 3 lines 16-57, column 7 lines 44-61. The desentizing agent is potassium nitrate. See column 4 lines 6-16. Carbamide peroxide is added to the composition. See column 3 line 58 – column 4 line 5. Fischer teaches that fluorides salts such as stannous fluoride can be added to the composition. See claim 14. Fischer teaches the addition of antimicrobial cetyl pyridinium bromide to the composition. See column 9 lines 27 – 36. Fischer also teaches that stabilizers such as EDTA are added to the composition to act as ion scavengers. See column 9 lines 38-45. Fischer teaches that the composition is applied to teeth for desensitizing and whitening teeth. Fischer teaches the that the composition can be applied to teeth by way of a dental tray. See column 10 line 7 – column 13 line 10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15,17,21-26,28,36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12,15,16 of U.S. Patent No. 5851512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desentizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent.

Claims 1-15,17,21-26,28,36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10,13,14 of U.S. Patent No. 5985249. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desentizing agent (potassium nitrate, citric acid),

a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent.

Claims 18-20,27,29-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,10-20 of U.S. Patent No. 6368576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desentizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray.

Claims 1-15,17,21-26,28,36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,11,13-19,23-26 of U.S. Patent No. 6309625. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desentizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent.

Claims 1-15,17 -40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desentizing agent

(potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

ALTON N. PRYOR
PRIMARY EXAMINER

Alton Pryor, AU 1616
August 1, 2003